

Docket No.: PF-0066-2 DIV

REMARKS

Entry of the amendments is proper

A response to the Office Action of January 29, 2003 was previously filed on March 20, 2003. According to the Advisory Action of July 8, 2003, the amendments and arguments filed September 15, 2001 have overcome the rejections of claims 39-42 under 35 U.S.C. § 112, second paragraph. However, these amendments were not deemed sufficient to overcome the remaining enablement rejection of claims 39 and 41 under 35 U.S.C. § 112, first paragraph.

Claims 13, 17, and 19-42 are pending in the application. Claims 13, 17, and 19-38 are withdrawn as being drawn to non-elected inventions. Applicants reserve the right to prosecute the non-elected claims in subsequent divisional applications. Claim 39 has been amended to further clarify the intended subject matter of the claimed invention. No new matter has been added by these amendments. The present amendments do not introduce any new issues, and place the subject application in condition for allowance and/or simplifies issues for appeal. Therefore, entry of the amendments is proper and is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph:

The rejection of claims 39 and 41 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement was maintained. In the Advisory Action mailed July 8, 2003, the Examiner asserts that the specification does not provide enablement for the claimed variants and biologically active fragments of SEQ ID NO:2, because the specification does not teach how to differentiate stem cells from non-stem cells. The Examiner further notes that while the specification has taught residues which are conserved across a number of stem cell antigens and would be likely to be important for function, these limitations are not part of the claim (Advisory Action, page 3).

In order to further clarify the intended meaning of the claims, Applicants have amended claim 39(b) to recite "an amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2, wherein said amino acid sequence conserves amino acid residues C₂₃, C₂₆, C₄₁, C₄₈, C₆₉, C₇₃, and N₉₆ and is expressed on the surface of cells." The recited amino acid residues are disclosed to be conserved among five different stem cell antigens (see the specification, page 6, lines 15-19). The numbering of the amino acid residues is based upon the SCAH-2 sequence as shown in Figure 3.

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In addition, claim 39(b), as amended herein, no longer recites variants that are expressed on the surface of stem cells, but variants that are expressed on the surface of cells. Thus one of skill in the art would understand how to identify sequences encompassed by the claims without requiring a detailed definition of stem cells.

Claim 39, as amended herein, no longer recites biologically active fragments; thus the rejection as it pertains to this aspect of the claims is moot.

Claim 39, as amended herein, recites immunologically active fragments of the claimed variants of 39(b), as suggested by the Examiner in a telephone interview on September 4, 2003. Given that the claimed variant sequences of claim 39(b) are described by the specification, one of ordinary skill in the art would understand how to make immunologically active fragments of these variants, using the guidance provided in the specification at, for example, page 38, lines 15-28. One of ordinary skill in the art would also understand that these immunologically active fragments could be used in a similar manner as the immunologically active fragments of SEQ ID NO:2, for example in diagnostic assays for diseases characterized by expression of SCAH-2 variants (specification, page 20, lines 5-29). Thus the recited immunologically active fragments of the variants of claim 39(b) are adequately described and enabled by the specification.

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CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,
INCYTE CORPORATION

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